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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,946	01/22/2001	Francois Mallet	028662.96	1475

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Supplemental
Notice of Allowability**

Application No.

09/680,946

Examiner

Jeffrey Fredman

Applicant(s)

MALLET ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
2. ☒ The allowed claim(s) is/are 1-20 and 22-53.
3. ☒ The drawings filed on 06 October 2000 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/053,498.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date ____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.


JEFFREY FREDMAN
PRIMARY EXAMINER

SUPPLEMENTAL REASONS FOR ALLOWANCE

1. This supplemental action is mailed to correct the indication of which claims were actually allowed.

2. The status of the claims is as follows:

Claims 1-20 and 22-53 are allowed.

3. The following is an examiner's statement of reasons for allowance: There are several reasons why the claims are allowed. For claims 1-20 and 22-49, these claims require a denaturation or initial extension step where the sample is heated to a temperature in a range from 55-75 C. Singer-Sam uses AMV as the reverse transcriptase and from the previous prosecution with the Shimomaye reference, it is clear that the AMV reverse transcriptase rapidly loses activity as the temperature increases, with 50% incorporation at 50 C and 10% incorporation at 55 C (see page 27 of Shimomaye). Consequently, the ordinary practitioner would not expect AMV to function at 55 C and there would therefore be no motivation to denature or extend at this temperature with the system of Singer-Sam. On the other end, the recently submitted Shaffer paper performs RT-PCR with only one enzyme, Taq polymerase, which has both DNA polymerase and reverse transcriptase activities. While Taq is certainly functional in the range of 60-75 C, Shaffer teaches a denaturation step at 94 C (see figure 1a). While this may not teach away from lower temperatures as used in the claims, there would be no motivation to denature in the lower temperature range of 60-75 C for Shaffer since 94 C will certainly do a better job of denaturing and since Taq is perfectly stable at 94 C. Therefore, an ordinary practitioner would have no reason to

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use a lower temperature that would not denature as well as 94 C and there is no motivation found in the art to suggest lowering the denaturation temperature of Shaffer's assay to the range of 60-75 C. Therefore, claims 1-20 and 22-49 are novel and unobvious over the cited prior art. With regard to claims 50-53, Sellner teaches away from ratios of RT to Taq of 2 to 8, teaching that any higher ratio than 3:2 inhibits Taq activity. Therefore, claims 50-53 are not taught by Sellner or Singer-Sam and there is a teaching away from forming an obviousness rejection. Therefore these claims are also novel and unobvious over the cited prior art.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
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